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And the first than the state of	<ol> <li>See Transmittal Form (attached hereto in duplicate)</li> <li>Specification [Total Pages 13]</li> <li>(Preferred arrangement set forth below)         <ul> <li>Descriptive Title of the Invention</li> <li>Cross References to Related Applications</li> <li>Statement Regarding Fed sponsored R&amp;D</li> <li>Reference to Microfiche Appendix</li> <li>Background of the Invention</li> <li>Brief Summary of the Invention</li> <li>Brief Description of the Drawings (if filed)</li> <li>Detailed Description</li> <li>Claim(s)</li> <li>Abstract of the Disclosure</li> </ul> </li> <li>Drawing(s)(35 USC 113) [Total Sheets ]</li> <li>Oath or Declaration</li> <li>Mewly executed (original or copy)</li> </ol>			8. de 9. (v	. Nucleotide a Submission . Computer F Paper Copy . Statement v  . ACCOMPA . Assignment . ASsignment . ASSIGNMENT . Brownent is a . English Tr . Informatio . (IDS)/PTO Preliminar . Return Re	ne Computer Program ( and/or Amino Acid Sequent (if applicable, all necessated able Copy (identical to computer coverifying identity of above (INTING APPLICATION of Papers (cover sheet & (INTING APPLICATION of Amendment of Amend	uence essary) opy) copies PARTS Attorney pplicable) itations
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Telephone: (732) 524-1214 Fax: (732) 524-2808  19. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED							
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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Clemence K. Dartey and Thomas E. Sox

For : LONG CHAIN ALCOHOLS PROVIDED IN EDIBLE OILS

# Express Mail Certificate

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Date of Deposit: December 15, 1999

I hereby certify that this complete application, including specification pages, claims, Declaration and Power of Attorney, and an Assignment, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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## LONG CHAIN ALCOHOLS PROVIDED IN EDIBLE OILS

# 5 Related Applications

This application is being concurrently filed with two additional applications. These related applications are entitled Encapsulated Long Chain Alcohols, US Serial Number yy/yyy,yyy (Attorney Docket MCP-234) and Long Chain Alcohols Admixed in Sterol Compounds, US Serial Number zz/zzz,zzz (Attorney Docket MCP-235), the contents of these applications incorporated by reference as if set forth in their entirety.

## Field of the Invention

The present invention describes a method of obtaining uniform distribution of a long chain alcohol or a mixture of such alcohols in a comestible product by dissolving or suspending the long chain alcohol in an edible oil.

## **Background** of the Invention

Long chain alcohols are known to have beneficial effects on human health. Researchers have reported that a blend of long chain alcohols obtained from sugar cane wax was effective in lowering serum cholesterol in rats. Sho, H., Chinen, I., and Fukuda, N., J. Nutr. Sci. Vitaminol. 30:553 (1984). In addition, US Patent No. 5,856,316 discloses the use of a mixture of long chain alcohols from sugar cane wax for lowering serum cholesterol in humans.

From the above disclosures it is apparent that long chain alcohols have important properties for improving the health of humans and animals. These beneficial properties include improving stamina, lowering blood cholesterol levels, and decreasing platelet aggregation. One desirable route for ingesting these alcohols is in food or beverage products. However, these long chain alcohols are very insoluble in water, and the very small amounts of these long chain alcohols needed to produce beneficial health effects makes content uniformity of long chain alcohols in a dry blending operation very difficult to achieve. Therefore, a means is needed for incorporating these long chain alcohols into food or beverage products in a manner that yields a uniform and consistent distribution of these materials in the comestible product.

Expensive and difficult measures have been disclosed to overcome these problems. For example, EP 801904 A1, describes the use of long chain alcohols (defined as alcohols having more

VIA EXPRESS MAIL NO. EL327264914 - MAILED DECEMBER 15, 1999 than 20 carbon atoms) in continuous fat phase compositions containing particulate sweeteners. The incorporation of the long chain alcohols at about 0.1% to about 0.4% was reported to decrease the viscosity of confectionery coatings made with this composition. All of the described compositions contained a particulated sweetener in addition to a chocolate material and a vegetable oil.

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Similarly, WO 98/47385 discloses a fat emulsion with a blend of emulsifiers created by the blending of a partial glyceride with a phospholipid and a long chain alcohol having a chain length of greater than  $C_{20}$ . The total weight of the glyceride and phospholipid in the composition must be greater than about 0.02 weight percent.

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Despite the teachings of these disclosures, there is an ongoing need to easily incorporate long chain alcohols into food products so that the advantageous effects of these alcohols can be achieved.

#### Summary of the Invention

The present invention provides a method of providing a desirable distribution of long chain alcohols in a food or beverage product. More specifically, this process comprises dissolving or suspending the long chain alcohol in an edible oil, and then incorporating this edible oil into a food or beverage product. In one embodiment the present invention is a method for preparing a long chain alcohol in an edible oil material comprising: providing an edible oil substantially free of medium chain triglycerides composed of C<sub>8</sub>-C<sub>10</sub> triglycerides and less than about 12 weight percent linolenic acid; providing a long chain alcohol; admixing said edible oil and long chain alcohol in the presence of an energy source such that the long chain alcohol is admixed in the oil; said long chain alcohol/edible oil admixture is stable and substantially free of an emulsifier or surfactant and having a viscosity of less than about 200 centipoise as measured at 70 °F at 60 revolutions per minute.

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A second embodiment of the invention provides the composition made by the method of the invention. In a third embodiment the composition of the present invention is employed to reduce the cholesterol level of a vertebrate that consumes an effective amount of the composition.

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# **Detailed Description of the Invention**

The present invention provides a method for incorporating long chain alcohols into an oil matrix without the need to add emulsifiers, surfactants or penetrant enhancers. The method includes the use of heat or mechanical energy or other suitable energy sources in order to make the long chain alcohols soluble in the lipid matrix. In a preferred embodiment the lipid matrix is an oil, preferably

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an oil derived from a vegetable source. Suitable oil sources include sunflower, safflower, corn, soybean, canola, mixtures of these oils and the like.

As used herein, long chain alcohols are understood to include saturated and unsaturated alcohols which contain more than about 90 weight percent C<sub>20</sub> or longer, primarily aliphatic alcohol materials. For the greatest health benefit it is preferred that the long chain alcohols be predominately, greater than 50 weight, percent octacosanol (C<sub>28</sub>), preferably more than 65 percent and more preferably greater than about 70 weight percent. As used herein policosanol is understood to be a mixture of long chain alcohols ranging from C<sub>20</sub> to C<sub>36</sub> preferably with greater than 65 weight percent C<sub>28</sub>. Common distribution and concentration ranges of the various components of policosanol are found in US Patent 5,856,316, the contents of which are incorporated by reference as set forth in its entirety. These long chain alcohols are available from various natural sources, most preferably from sugar cane wax. The long chain alcohols can also be synthesized using techniques well known in the art.

Policosanol is soluble at about 160 - 180 °F in suitable lipid matrices such as vegetable oils and fat-soluble emulsifiers, vitamins and the like. Suitable methods for incorporating policosanol or other long chain alcohol into the oil, include heating by conventional means such as: heating elements or open flame; radiation sources and other ultrasonic wave generating equipment; as well as mechanical means such as agitation, homogenization, and the like.

In a preferred embodiment of the present invention, the long chain alcohol is ground into a microcrystalline form in order to improve the stability of the oil/long chain alcohol mixture. Suitable grinding techniques include hammermill, cryogenic rotary mills and the like. The particle size of the ground material is less than about 100 microns, preferably from about 20 to about 80 and most preferably from about 30 to about 60 microns.

Typically the level of long chain alcohol incorporated into the oil is from about 0.1 to about 5 percent, preferably from about 0.5 to about 3 and most preferably from about 0.8 to about 2 weight percent. Those with skill in the art will appreciate that the concentration of the long chain alcohol will vary depending on various factors such as the dosage desired, the serving size and the solubility of the long chain alcohol in a particular oil.

One advantage of the present invention is that the long chain alcohol remains stable in the edible oil. As used herein, stable is understood to mean that the long chain alcohol does not precipitate, crystallize out, or separate when dissolved in the edible oil.

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Another advantage of the present invention is that the viscosity of the policosanol-enriched oil is such that the admixture remains suitable for many applications. Unlike other disclosures, the present invention does not have to be made into a high viscosity paste before being incorporated in a comestible. The long chain alcohol/edible oil mixture has a viscosity of less than about 200 centipoise, preferably from about 10 to about 150 and most preferably from 50 to about 130 centipoise. The viscosity is measured at 70 °F using a Brookfield Viscometer Model DV-II<sup>+</sup>, spindle #2 at 60 revolutions per minute for 10 seconds.

Once the long chain alcohol has been suspended or dissolved into the oil matrix, those with skill in the art will readily understand how to incorporate the long chain alcohol/oil matrix into food products designed to lower cholesterol. The long chain alcohol/oil preparations can be used as a spray oil for cookies and crackers or can be used to formulate a number of cholesterol lowering food products including salad dressings, mayonnaise dressings, nutrition bars, beverages, juices, low fat ice creams, yogurts and frozen yogurts, non-dairy creamers, cheese spreads, milk products, confectioneries, chocolate-containing products such as cakes and cookies, margarine, and other spreads suitable for application on breads and the like. The long chain alcohol/oil preparations can also be formulated into pharmaceutical preparations, including tablets, soft gelatin capsules, especially those containing liquid formulations, such as suspensions, emulsions, solutions and the like.

The present invention can be provided in foods in which water is the continuous phase, such as salad dressings and mayonnaise. In a preferred embodiment of the invention the long chain alcohol/edible oil product of the present invention is incorporated into a product which has a continuous oil phase such as spreads and margarines. The long chain alcohol typically comprises from about 0.0001% to about 0.4% of the comestible product, preferably from about 0.007 to about 0.14 and most preferably from about 0.018 to about 0.071 weight percent of the comestible product.

Typically the level of the long chain alcohol is from 0.1 to about 100 milligrams/servings; preferably from about 0.5 to about 20 milligrams/serving and most preferably from about 2 to about 10 milligrams/servings.

The present invention provides an edible oil/ long chain alcohol mixture that does not require the incorporation of high levels of linolenic acid in the edible oil as was previously disclosed in the art. Further the present invention does not require the addition of triglycerides, particularly  $C_{8}$ - $C_{10}$  triglycerides; or other surfactants or emulsifiers in order to form the admixture. Because the edible oil/long chain alcohol does not need to incorporate these other agents, the admixture can be

more readily formulated into other comestible products. Substantially free as used herein is understood to mean less than 1.0 weight percent, preferably less than 0.5 and most preferably less than 0.1 weight percent.

The comestible product of the present invention can be used to reduce the cholesterol level of vertebrates that consume the comestible. Vertebrates include reptiles, mammals, fish and the like, with humans being most preferred.

The following examples are provided as specific embodiments of the present invention. Other modifications of this invention will be readily apparent to those skilled in these arts without departing from the scope of the present invention.

#### Example 1

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One percent policosanol in a vegetable oil was prepared by adding 2.0 g policosanol (CHOLESSTANOL (95 % pure sugarcane wax material from Garuda International)) to 198.0 g soybean salad oil in a 400-ml PYREX glass beaker. The beaker was placed in a waterbath on a stove. The stove was turned on and the soybean oil/policosanol mixture was stirred gently by hand with a stainless steel spatula. The policosanol/soybean oil dispersion was heated and stirred until policosanol melted and solubilized in the oil at 160 - 180 °F. The viscosity of the policosanol soybean oil preparation was measured at 170, 120, 80 and 70 °F using the Brookfield Viscometer Model DV-II<sup>+</sup>, Spindle #2 @ 60 rpm for 10 seconds. This viscosity data is presented in Table 1. Table 1 also presents results on soybean salad oil preparations containing 0, 0.1, 0.2, 0.4 and 0.6 weight % policosanol made by similar processes.

The results showed no significant differences between the viscosities of the samples at 120 °F and also at 176 °F regardless of the policosanol concentration. However, at 80 and 70 °F, the viscosities of the samples increased as the concentration of policosanol in the oil samples increased. The samples were stored at room temperature and observed the next day. The policosanol preparations developed translucent gel-like precipitates. After a few days at room temperature, the gel-like materials developed layers and gel-like precipitates. The gel-like precipitates dissolved when the samples were heated to about 180°F.

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Table 1. Effect of Policosanol Concentration on Viscosity of Soybean Oil

% Policosanol	Viscosity @	Viscosity @	Viscosity @	Viscosity @
Concentration	176 °F	120 °F	80 °F	70 °F
0	15.0 cP	26.0 cP	43.3 cP	59.5 cP
0.10	14.5 cP	27.0 cP	43.5 cP	64.5 cP
0.20	14.5 cP	28.0 cP	46.5 cP	82.0 cP
0.40	15.0 cP	28.0 cP	49.5 cP	119.0 cP
			50.5 D	110 0 P
0.60	15.0 cP	28.0 cP	53.5 cP	112.0 cP
1.00	14.5 aD	28 A a D	105 0 aP	129.0 <b>cP</b>
1.00	14.5 cP	28.0 cP	105.0 cP	129.0 CF

## Example 2

A policosanol preparation from the preceding example containing 1.0 % policosanol in soybean oil was used to produce cholesterol lowering regular and light (reduced fat) margarine spreads containing plant stanol esters. The formulations are shown in Table 2. The oil phase ingredients, liquid soy bean oil (#9196 Ventura) and partially hydrogenated soybean oil (#9494 Ventura), Canola oil, plant stanol esters, monoglycerides, lecithin and hexaglycerols were blended together in a margarine emulsion tank. The blend was mixed slowly and heated to 160 °F to melt into a clear liquid oil blend. The policosanol preparation, butter flavor, vitamins A & D blend and beta-carotene were added and blended into the oil phase.

The aqueous phase was prepared by blending potassium sorbate, ethylenediaminetetra acetic acid (EDTA), citric acid and salt in the water in an aqueous phase tank or in a stainless steel container. While stirring the oil phase at high speed, about 800 rpm, the aqueous phase was poured slowly into the oil phase to produce the margarine spread emulsion at approximately  $130 \pm 5$  °F. The margarine was prepared by processing the emulsion through a scrape surface heat exchanger (A-unit) and then through a pin worker (B-unit) and finally through a filler unit. The finished margarine spread was filled into suitable containers. The cooling system was adjusted during the processing of the margarine spread emulsion to maintain the temperature of the finished spread at the filler unit at about 40 - 60 °F. The margarine spreads processed as indicated exhibited physical and sensory properties characteristic of regular and light margarine spreads.

Table 2. Composition of a Typical Cholesterol-Lowering Margarine Spread Containing Policosanol.

	Regular	Light Margarine
	Margarine	Spread
	Spread	
Oil Phase Ingredients	Wt. Pounds	Wt. Pounds
Liquid Soybean Oil	7.44225	23.64125
Partially Hydrogenated Soybean Oil	11.00000	0
Liquid Canola Oil	30.00000	0
Plant Stanol Esters (Raisio)	21.55000	21.55000
Mono-glycerides	0.30000	0.40000
Lecithin	0.20000	0.30000
Hexaglycerol Distearate, POLYALDO 6-2-S (Lonza)	0.10000	0.10000
Hexaglycerol Mixed Esters, CAPROL ET (A.C. Humko)	0	0.10000
Butter Flavor (Firmenich)	0.05000	0.05000
Vitamin A &D Blend (Roche)	0.00625	0.00625
Beta-Carotene	0.00150	0.00250
Policosanol/Oil Blend, (1:99 w/w) (CHOLESSTANOL	4.35000	4.35000
Policosanol from Garuda International)		
Aqueous Phase Ingredients		
Water	22.88550	47.38300
Salt	2.00000	2.00000
Citric Acid	0.00750	0.01000
Calcium Disodium EDTA	0.00700	0.00700
Potassium Sorbate	0.10000	0.10000
TOTAL	100.00000	100.00000

5 Both the regular and light margarine spreads contained approximately 3.5 milligrams of policosanol per 8 gram serving size.

## Example 3

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The policosanol preparation, 1.0 % policosanol in soybean oil, was used to prepare ranch, French, creamy Italian and thousand island dressings containing plant stanol esters. Table 3 showed the composition of a ranch dressing produced. The process for preparing the ranch dressing

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in the pilot plant involved the following processing steps. The preservatives (potassium sorbate and sodium benzoate) and EDTA were dissolved in the dressing emulsion tank on a pilot plant size Charlotte Colloid Mill unit. KELTROL T xanthan gum and KELCOLOID LVF (both from Kelco) were dispersed in a portion of the soybean oil (one part gums and 2 - 5 parts oil). The gum dispersion was hydrated in the water for 10 minutes using medium speed agitation. This was followed by blending in the vinegar and lemon juice, sugar, salt, ranch seasonings, buttermilk solids and titanium dioxide. After mixing the blend at high speed for 10 minutes, the polysorbates were melted and added with the liquid egg yolk and mixed for about one minute. The policosanol oil blend was mixed into the salad oil. The stanol esters (if present) and CAPROL ET (A. C. Humko) were added to the soybean salad oil and the mixture was heated to approximately 130 °F to melt and dissolve CAPROL and stanol esters. While mixing the aqueous phase blend at high speed, the oil blend containing stanol esters (if present), CAPROL ET, policosanol oil blend, vitamin E and tocopherol preparation were added slowly to form the dressing emulsion. The coarse emulsion produced was then milled through a colloid mill with 0.02" gap opening. After the viscosity, titratable acidity, salt and pH were determined and approved, the milled dressing was pumped through a filling unit and bottled.

Table 3. Compositions of Typical Cholesterol-Lowering Ranch Dressings Containing Policosanol with or without Stanol Esters

	With Stanol	Without Stanol
	Esters	Ester
Ingredient Composition	Weight	Weight
	(Pounds)	(Pounds)
Water	33.0807	36.6479
Vinegar, 120 Grain, White distilled	7.0000	7.0000
Sugar, Fine Granulated	4.9000	4.9000
Ranch Seasoning #139 (Ventura)	4.2000	4.2000
Cultured Buttermilk Solids #64414 (Armour)	1.6000	1.6000
Salt	0.7000	0.7000
Calcium Disodium EDTA	0.0060	0.0060
Egg Yolk, Liquid, 10 % Salt	0.3600	0.3600
KELTROL T Xanthan Gum (Kelco)	0.3500	0.3500
Polysorbate 60, Tween 60	0.3000	0.3000
Lemon Juice Concentrate, 400 GPL	0.2500	0.2500
KELCOLOID LVF, (Kelco)	0.1750	0.1750

Polysorbate 80, TWEEN 80	0.1600	0.1600
Titanium Dioxide	0.1400	0.1400
Potassium Sorbate	0.0800	0.0800
Sodium Benzoate	0.0800	0.0800
Vitamin E Acetate (Roche)	0.0183	0.0183
Policosanol/soybean oil blend (1:99 w/w) (CHOLESSTANOL	1.2000	1.2000
policosanol from Garuda International)		
DL-Alpha-Tocopherol (Roche)	0.0082	0.0082
Calcium Disodium EDTA	0.0060	0.0060
Paprika Oleoresin 1000 ASTA	0.0019	0.0019
Soybean Oil, Salad Oil	38.8186	41.1967
Stanol Esters (Raisio)	5.9453	0.0000
CAPROL ET (A. C. Humko)	0.6200	0.6200
TOTAL	100.0000	100.0000

Both dressings contained approximately, 3.5 milligram of policosanol per 30 gram serving size.

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#### We claim:

5 1. A process for preparing a comestible product containing high molecular weight alcohols comprising:

providing a high molecular weight alcohol;

providing an edible oil containing less than about 12 weight percent linolenic acid that is substantially free of medium chain triglycerides composed of  $C_8$  to  $C_{10}$  fatty acids;

admixing said high molecular alcohols in said edible oil to form a high molecular weight alcohol/edible oil admixture that contains less than two weight percent high molecular weight alcohol; and combining said admixture with other components of a comestible product.

- 2. The process of claim 1 wherein the high molecular weight alcohol is policosanol.
- 3. The process of claim 1 wherein the high molecular weight alcohol is octacosanol.
- 4. The process of claim 1 wherein the edible oil is a vegetable oil.
- 5. The process of claim 1 wherein the comestible product is a non-continuous oil phase product.
  - 6. The process of claim 5 wherein the non-continuous oil phase product is a margarine.
- The process of claim 5 wherein the non-continuous oil phase product is a spread.
  - 8. The process of claim 5 wherein the non-continuous oil phase product is a salad dressing.
  - 9. The process of claim 4 wherein the non-continuous oil phase product is a mayonnaise.
  - 10. The process of claim 1 wherein the amount of the long chain alcohol admixed in the edible oil comprises from about 0.0001% to about 0.4 weight % of the comestible product.
- 11. The process of claim 1 wherein the amount of the high molecular weight alcohol admixed in the edible oil comprises from about 0.001% to about 0.01% of the comestible product.

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12. Method for preparing a long chain alcohol in an edible oil material comprising:

providing an edible oil substantially free of medium chain triglycerides composed of C<sub>8</sub>-C<sub>10</sub> triglycerides and containing less than about 10 weight percent linolenic acid; providing a long chain alcohol;

admixing said edible oil and long chain alcohol in the presence of an energy source such that the long chain alcohol is admixed in the oil; said long chain alcohol/edible oil admixture is stable and substantially free of an emulsifier or surfactant; and having a viscosity of less than about 200 centipoise as measured at 70 °F.

- 10 13. The method of claim 10 wherein the long chain alcohol and oil are heated to a temperature of from about 160 to about 180 °F.
  - 14. The method of claim 11 wherein the long chain alcohol is provided at a level of from about 0.1 to about 2 weight percent based upon the level of the oil.
  - 15. The method of claim 12 wherein the long chain alcohol is policosanol.
  - 16. The method of claim 13 wherein the policosanol has an octacosanol content of greater than about 65 weight percent.

17. A composition comprising:

a stable edible oil /long chain alcohol admixture substantially free of an emulsifying or surfactant agent, the edible oil substantially free of medium chain triglycerides composed of  $C_8$ - $C_{10}$  triglycerides and containing less than about 10 weight percent linolenic acid;

- 25 the admixture having a viscosity of less than about 200 centipoise as measured at 70 °F.
  - 18. The composition of claim 15 wherein the long chain alcohol is from about 0.1 to about 2 weight percent of the total composition weight.
- 30 19. The composition of claim 16 wherein the long chain alcohol is policosanol.
  - 20. A method of reducing cholesterol in a vertebrate comprising: providing an effective amount of the comestible product of claim 1.
- 21. The method of claim 20 wherein the comestible contains about 0.1 to about 100 milligrams of high molecular weight alcohol per serving size.

22. A method of reducing cholesterol in a vertebrate comprising administering an effective amount of the composition of claim 17.

# **Abstract of the Invention**

The present invention provides a method for incorporating long chain alcohols into edible oils. The long chain alcohol/edible oil admixture is then suitable for use in preparation of various foods. The long chain alcohol is added by the introduction of energy and in a preferred embodiment in the absence of surfactants and emulsifiers.

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## DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

### LONG CHAIN ALCOHOLS PROVIDED IN EDIBLE OILS,

the specification of which

check one)	oxtimes is attached hereto.		
	☐ was filed on as		
	Application Serial No.		
	and was amended on (if applicable)		

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, \$119 (a)-(d) or \$365(b) of any foreign application(s) for patent or inventor's certificate, or \$365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

# Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Under 35 U	
			☐ YES	□ NO
-			☐ YES	□ NO
			☐ YES	☐ NO

I hereby claim the benefit under Title 35, United States Code, \$119(e) of any United States provisional application(s) listed below:

(Application Number)	(Filing Date)
(Application Number)	(Filing Date)

I hereby claim the benefit under Title 35, United States Code, \$120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, \$112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, \$1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
Application Serial No.	Filing Date	Status

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Audley A. Ciamporcero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Andrea L. Colby (Reg. #30,194), Michael Stark (Reg. #32,495), and Joseph F. Leightner (Reg. #34,209) One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

<pre>Inventor's Signature: Full Name of Sole   or First Inventor</pre>	Clemence K. Dartey  Date: 12/15/99
Citizenship: U.S.A. Residence: 56 Saddlebrook Drive, Post Office Address: Same as above	• • • •
<pre>Inventor's Signature: Full Name of Second Joint   Inventor, If Any Citizenship: U.S.A. Residence: 1105 Meetinghouse Roa Post Office Address: Same as above</pre>	Thomas E. Sox  Date: <u>Nec. 15, 1999</u> d, Ambler, PA 19002
Inventor's Signature: Full Name of Third Joint Inventor, If Any	

(Supply similar information and signature for fourth and subsequent joint inventors.)

Date: